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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,012	09/20/2001	John Lezdey	1434-K	3483

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EXAMINER	
COE, SUSAN D	
ART UNIT	PAPER NUMBER
1654	5

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/957,012	LEZDEY ET AL.	
	Examiner	Art Unit	
	Susan Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5,12,13 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4,6-11, 14-16, and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-20 are currently pending.

Election/Restrictions

2. Applicant's election with traverse of rheumatoid arthritis for species A and alpha 1-antitrypsin for species B in Paper No. 4, dated January 13, 2002 is acknowledged. The traversal is on the ground(s) that search of all of the species would not be burdensome to the examiner because all of the diseases from species A are related and all of the compounds from species B are related. This is not found persuasive because applicant has claimed three distinct compounds and at least three distinct diseases. In order to fully search these claims at least nine different searches, matching each compound with each disease, would have to be made. None of the prior art cited by applicant in the traversal would eliminate the need for all of the searches because none of them completely teach all of the claimed limitations. In the response, it seems that applicant admits that the three protease inhibitors are obvious over each other, but it is not clear if this is what applicant intends. Therefore, unless applicant is willing to clearly admit for the record that all of the species are obvious over each other, the search of all of the species is considered burdensome.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 5, 12, 13, and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

4. Claims 1-4, 6-11, 14-16, and 18-20 are examined on the merits.

Priority

Applicant's claim for priority as a continuation-in-part of US Appl. No. 09/885,654 is acknowledged. The parent application does not enable the use of protease inhibitors to treat non-pulmonary diseases such as rheumatoid arthritis and diseases characterized by matrix metallo-proteinases. Therefore, the claims drawn to treating these diseases are not granted a priority date based on the filing date of the parent application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 6-9 and 18-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite "said protease inhibitor." The antecedent basis for is unclear. It is assumed that in claims 6-9 and 18-20 the phrase "said protease inhibitors refer to the three proteins, alpha 1-antitrypsin, secretory leucocyte protease inhibitor, and alpha 2-macroglobulin; however, in order to use the term "said," the phrase following "said" must have literal antecedent basis in the claim. The only mention of "protease inhibitor" in claims 1 and 15 is "secretory leuocyte protease inhibitor;" therefore, the phrase "said protease inhibitor" only has the proper antecedent basis for secretory leuocyte protease inhibitor. For the sake of examination, it is assumed that applicant means for claims 6-9 and 18-20 to apply to all of the claimed proteins. Thus, the claims will be examined in accordance with the elected species of alpha-1-antitrypsin, but appropriate clarification of the antecedent basis is needed. In order to

correct this problem, it is suggested that applicant amend claims 6-8 and 18-20 to replace "said protease inhibitors" with "said proteins".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-4, 6-9, 14-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable WO 00/51623 over in view of US Pat. No. 4,496,689 and WO 99/55310.

Applicant's claims are drawn to a method of treating rheumatoid arthritis by orally administering a stabilized alpha-1-antitrypsin.

WO '623 teaches treating rheumatoid arthritis by orally administering alpha-1-antitrypsin. The alpha-1-antitrypsin composition also contains antioxidants such as glutathione (see page 13, lines 15-26, page 15, line 6, and page 19, section 5.7). However, WO '623 does not specifically teach that the alpha-1-antitrypsin is conjugated, crystallized, or crosslinked.

US '689 teaches that the stability of alpha-1-antitrypsin is increased if it is conjugated with dextran or polyethylene glycol (see claims 6 and 25-32). The methods of US '689 would also produce crosslinked proteins.

WO '310 teaches stabilizing alpha-1-antitrypsin by crosslinking and crystallization (see page 38).

Based on US '689 and WO '310, a person of ordinary skill in the art would reasonably expect that the alpha-1-antitrypsin used in the method of WO '623 could have improved stability if conjugated, crystallized, or crosslinked using the methods taught by US '689 and WO '310. Thus, based on the combined disclosures of WO '623, US '689, and WO '310, a person of ordinary skill in the art would be motivated to treat rheumatoid arthritis using an alpha-1-antitrypsin stabilized by conjugation, crystallization, or crosslinking.

WO '623 does teach using antioxidants with the alpha-1-antitrypsin, but the reference does not specifically teach using the antioxidants catalase and mannitol claimed by applicant. However, these compounds are both well known antioxidants; therefore, a person of ordinary skill in the art would reasonably expect that they could be used as the antioxidants in the composition of WO '623. Thus, an artisan of ordinary skill would have been motivated to use catalase and mannitol in combination with alpha-1-antitrypsin.

11. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/51623, US Pat. No. 4,496,689 and WO 99/55310 as applied to claims 1-4, 6-9, 14-16 and 18-20 above, and further in view of US Pat. No. 4,743,596.

As discussed above, the combined disclosures of WO '623, US '689, and WO '310 teach treating rheumatoid arthritis using an alpha-1-antitrypsin stabilized by conjugation, crystallization, or crosslinking. However, the references do not specifically disclose using a corticosteroid.

US '596 teaches that a corticosteroid, prednisone, can be orally administered to treat rheumatoid arthritis (see claims). Based on this teaching, a person of ordinary skill in the art would reasonably expect that administering a corticosteroid with alpha-1-antitrypsin would be

beneficial because the are both known to be used for treating rheumatoid arthritis. Therefore, an artisan of ordinary skill would have been motivated to use a corticosteroid in combination with stabilized alpha-1-antitrypsin to treat rheumatoid arthritis.

12. Claims 1, 4, 6-9, 14-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable US Pat. No. 5,114,917 in view of US Pat. No. 4,496,689 and WO 99/55310.

US '917 teaches treating rheumatoid arthritis by orally administering alpha-1-antitrypsin (see column 2, lines 49-57 and Example III). However, US '917 does not specifically teach that the alpha-1-antitrypsin is conjugated, crystallized, or crosslinked.

US '689 teaches that the stability of alpha-1-antitrypsin is increased if it is conjugated with dextran or polyethylene glycol (see claims 6 and 25-32). The methods of US '689 would also produce crosslinked proteins.

WO '310 teaches stabilizing alpha-1-antitrypsin by crosslinking and crystallization (see page 38).

Based on US '689 and WO '310, a person of ordinary skill in the art would reasonably expect that the alpha-1-antitrypsin used in the method of US '917 could have improved stability if conjugated, crystallized, or crosslinked using the methods taught by US '689 and WO '310. Thus, based on the combined disclosures of US '917, US '689, and WO '310, a person of ordinary skill in the art would be motivated to treat rheumatoid arthritis using an alpha-1-antitrypsin stabilized by conjugation, crystallization, or crosslinking.

13. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,114,917, US Pat. No. 4,496,689 and WO 99/55310 as applied to claims 1, 4, 6-9, 14-16 and 18-20 above, and further in view of US Pat. No. 4,743,596.

As discussed above, the combined disclosures of US '917, US '689, and WO '310 teach treating rheumatoid arthritis using an alpha-1-antitrypsin stabilized by conjugation, crystallization, or crosslinking. However, the references do not specifically disclose using a corticosteroid.

US '596 teaches that a corticosteroid, prednisone, can be orally administered to treat rheumatoid arthritis (see claims). Based on this teaching, a person of ordinary skill in the art would reasonably expect that administering a corticosteroid with alpha-1-antitrypsin would be beneficial because the are both known to be used for treating rheumatoid arthritis. Therefore, an artisan of ordinary skill would have been motivated to use a corticosteroid in combination with stabilized alpha-1-antitrypsin to treat rheumatoid arthritis.

14. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,114,917, US Pat. No. 4,496,689 and WO 99/55310 as applied to claims 1, 4, 6-9, 14-16 and 18-20 above, and further in view of US Pat. No. 5,362,733.

As discussed above, the combined disclosures of US '917, US '689, and WO '310 teach treating rheumatoid arthritis using an alpha-1-antitrypsin stabilized by conjugation, crystallization, or crosslinking. However, the references do not specifically disclose using antioxidants.

US '733 teaches using antioxidants to treat rheumatoid arthritis (see column 1, first two paragraphs). Based on this teaching, a person of ordinary skill in the art would reasonably expect that administering an antioxidant with alpha-1-antitrypsin would be beneficial because the are both known to be used for treating rheumatoid arthritis. Therefore, an artisan of ordinary

skill would have been motivated to use an antioxidant in combination with stabilized alpha-1-antitrypsin to treat rheumatoid arthritis.

The reference does not specifically teach using the antioxidants glutathione, catalase and mannitol as claimed by applicant. However, these compounds are all well known antioxidants; therefore, a person of ordinary skill in the art would reasonably expect that they could be used as the antioxidants to treat arthritis as described by the reference.

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
February 6, 2003

LEON B. LANKFORD, JR.
PRIMARY EXAMINER